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TECHNOLOGY TRANSFER MANAGEMENT IN PHARMACEUTICAL INDUSTRY THROUGH FREEDOM TO OPERATE (FTO) UTILIZATION

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ABSTRACT

Intellectual property rights (IPR) particularly patent is one of important capital to enhance social, technological and economic development. Patent resulted by research and development activity (R&D) in creating technology. R&D institution like research institute, university and industry not always transferred and disseminated their technologies to other stakeholders. High cost in R&D activity and licensing cause of handicap in mastering and dissemination technology. One solution is freedom to operate utilization. Patent is a form of technology capitalization of an invention that has a time limit of protection. Along with expiration of protection, technology that previously had a certain exclusivity become public domain means that wider community can utilize these technologies freely. Based on principle of territoriality, patent is not registered in a country can also be used freely. Limitation of research funding and urgency of problems to be resolved in community then management tehnology transfer through utilization of patent by freedom to operate analysis is an appropriate strategy in order to provide wider benefits and solve problems faced by community. As we know that pharmaceutical industry is technology driven, research intensive, high profit-high risk, long process and duration.

The development of each therapies and medicine take long time and phase. Therefore only developed country and multinational companies that able mastering pharmaceutical market and many countries only as consumers. Developing countries as consumers have not many choice to produce by themselves because of limitation in budget and technology. So, technology transfer by freedom to operate utilization is one way to shortcut the time and budget by developing countires to participate and take a part in pharmaceutical industry development. This study aimed to describe how to analyze freedom to operate status in pharmaceutical technology and which can be used to encourage technology transfer so that technology can be utilized by users.

FTO needs comprehensive analysis : all IPR aspect, associated agreement and contracts such as license or material transfer agreement. But, in this study will focus patent aspect only. Dimension of FTO analysis divided by expiration of protection, teritorial protection and limited scope of claims. This study used qualitative research methodology with descriptive analysis approach literature studies and searching patent document in any database.

The patent search should be systematic, structured, documented properly will result accurate data. FTO analysis sources from patent search be able to map and manage technology that have freedom to operate status in all therapies and medicines aspects particularly process, composition, formulation, methods, apparatus related in pharmaceutical industry and so that stakeholders especially developing countries can be absorb and utilized in order to accelerate technology transfer.

KEYWORDS: Technology Transfer, Freedom to Operate, Pharmaceutical Industry

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Original Article

INTRODUCTION

Background

Intellectual Property Rights (IPRS)

Intellectual property rights (IPR) particularly patent is one of important capital to enhance social, technological and economic development. Patent resulted by research and development activity (R&D) in creating technology. R&D institution like research institute, university and industry not always transferred and disseminated their technologies to other stakeholders. High cost in R&D activity and licensing cause of handicap in mastering and dissemination technology. One solution is freedom to operate utilization. Patent is a form of technology capitalization of an invention that has a time limit of protection. Along with expiration of protection, technology that previously had a certain exclusivity become public domain means that wider community can utilize these technologies freely. Based on principle of territoriality, patent is not registered in a country can also be used freely. Limitation of research funding and urgency of problems to be resolved in community (Janodia et.al., 2008). Thus, tehnology transfer management through utilization of patent by freedom to operate analysis is an appropriate strategy in order to provide wider benefits and solve problems faced by community.

Research and Development plays vital role in creating these technologies. But not always research goal are shared to the stakeholders or users. There are severals aspects of technology transfer where pharmaceutical industry, university, research institutions and goverment can participate in disseminating the knowledge and know how and develop new medicine or enhance existing therapies. These research goal can be transfered to the stakeholders through commercialization pathway such as licensing. Licensing is one such aspect of technology transfer which is gaining prominence among pharmaceutical companies (Janodia et.al., 2008).

Technology Transfer

Technology trasnfer is sharing of skills, knowledge, technology among institutions to ensure that scientific and technological developments are accessible to a wider range. Identify research that has a potential commercial interest and develop a strategy to maximize utilization. Technology transfer is process remove a technology from technology producer to the users. Technology producers are research institute (public or private), industry, university, even individual. These technology producers in some conditions also be users. So there are many feedback and interaction between them. Technology transfer include open investment for domestic and foreign with stakeholders that mastered technology and market. Thus, must change paradigm that mastering of technology not only by research but also essentially is technology transfer (Janodia et.al., 2008).

Nowadays, pharmaceutical material industries supported by four main product are biopharmacy, vaccine, natural/herbal and chemist/syntetic. Almost 50 % of total pharmaceutical products based on chemist/syntetic product. Indonesia as rich country in material of medicine can take advantage in manufacturing base of upstream pharmaceutical industry. Technology of processing raw material be keyword to reduce depending from developed country in pharmaceutical industry. This technology must not started from research but can be taked from estabilished industry through technology transfer. Therefore stimulate massive investment from them not only capital movement but also technology movement (http://industri.bisnis.com).

Pharmaceutical Industry

As we know that pharmaceutical industry is technology driven, research intensive, high profit-high risk, long process and duration. The development of each therapies and medicine take long time and phase (Janodia e.al., 2008). Spatz and MacGee (2013) divided pharmaceutical or a drug is classified on the basis of their origin.

- Drug from natural origin: Herbal or plant or mineral origin, some drug substances are of marine origin.
- Drug from chemical as well as natural origin: Derived from partial herbal and partial chemical synthesis Chemical, example steroidal drugs
- Drug derived from chemical synthesis.
- Drug derived from animal origin: For example, hormones, and enzymes.
- Drug derived from microbial origin: Antibiotics
- Drug derived by biotechnology genetic-engineering, hybridoma technique for example
- Drug derived from radioactive substances.

Therefore only developed country and multinational companies that able mastering pharmaceutical market and many countries only as consumers. Developing countries as consumers have not many choice to produce by themselves because of limitation in budget and technology. So, technology transfer by freedom to operate utilization is one way to shortcut the time and budget by developing countires to participate and take a part in pharmaceutical industry development. This study aimed to describe steps how to analyze freedom to operate status in pharmaceutical technology and which can be used to encourage technology transfer so that technology can be utilized by users.

METHODS

This study used qualitative research methodology with descriptive analysis approach literature studies and searching patent document in any patent database.

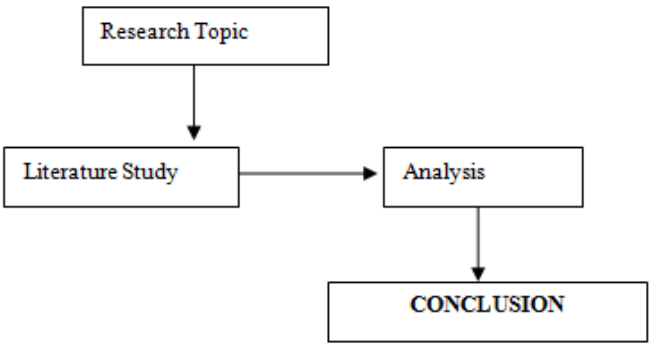

Figure 1: Research Step

RESULTS AND DISCUSSIONS

Technology Transfer in Pharmaceutical Industry

Pharmaceutical industry is technology driven, research intensive, high risk – high profit, complicated and long process. The development of various therapies and medicines takes multiyears, big investation and different phase where

regulatory approval is mandatory before launching any product to users. Many pharmaceutical firms do not have capacity to research, develop and follow the end stage as way to launch product. Thus, they transfer the technology to the big pharmaceutical industry that have strong capital to do each step from pre clinical until clinical test. This condition made multinational pharmaceutical company always superior and mastering pharmaceutical sectors from upstream until downstream. This is ascribed to strong protection of intellectual property such as patents. Restriction by developing country concerning the patents system the pharmaceutical field are usually based on series of of factors are product importation with development of technology. Both of them have implication (Janodia et.al., 2008). Product importation is more practice and do not need long time to get any medicine but depending of the other country is very high and product imported can not decide the price. Technology development needs big investation, long process and high risk but in the future will make independence of pharmaceutical product even be able to results IPR product that be strong capital to be commercialized.

The middle solution of this case is technology transfer without licensing mechanism. FTO opinion and analysis is one of win-win solution. FTO needs comprehensive analysis : all IPR aspect, associated agreement and contracts such as license or material transfer agreement. But, in this study will focus patent aspect only. Dimension of FTO analysis divided by expiration of protection, teritorial protection and limited scope of claims.

The keywords from this strategy is judgment prior art through searching. Priort art search is the most challenging activity in patentability (novelty, inventive step and industrial applicable) determination. The prior art search may be carried out for some reasons, like determining patentability of an invention, ground of patent invalidation, possibility to proceed with the research, development and/or commercial production, marketing or use of a new product or process. Research project proposal for all kind of research will have strong innovation and validation if doing search of prior art before. This activity will rise new improvement, innovation and do not repeat the same research (Sandal and Kumar, 2011).

Prior art for determining patentability and invalidation of patent claims constitute any type of public disclosure of the art, including patents, publication, books, posters, presentations, and prior public use. Prior art search for the development and/or commercial production, marketing or use a new product or process is commonly termed as Freedom to Operate (FTO) search. FTO is essentially legal concept, which can not absence of any third party valid intellectual property right (IPR) claims against a particular commercial operation. FTO search is generally focused on the country where the product is to be commercialized and includes only an expired patents and under-prosecution patent applications of the country. Therefore, the results of FTO analysis is expected to give signal of opportunity of marketing the product in focus in that country. This is one of the input used by technology managers to take strategic decisions in relation to product/process launch or even initiate R &D for realizing a particular product or process. The early preparation for an FTO analysis are crucial because they influence all the follows and determine the quality of the product or process (Sandal and Kumar, 2011).

As statement before, that in this study will focus patent aspect only. Dimension of FTO analysis divided by expiration of protection (public domain because time protection limit and unpayment annual fee), teritorial protection and limited scope of claims. FTO utilization needs strong, accurate and systematic analysis. This is steps that adopted from Sandal and Kumar (2011).

Understand the Field of Technology (Product or Process)

First step that must be done is understand the state of the art of the technology whether it is a product, process, or combination thereof. To understand the nature of technology, it can be disammbled into its fundamental components which are deconstructed.

Identify Keywords for Search

The keywords must be selected accurately such as all the broad as well as specific terms identifiying the invention in the definitely claims, element defining utility and cause of invention and similarity or synonym like biofuel or biosolar, bioreactor or biodigester, etc.

Identify the Database for Search

FTO analysis is specific in each country, as a patents is teritorial rights. Thus, same technology (product or process) but registered in different country, need different analysis and treatment too. It is important to combine searching in any database to get valid comprehensive information.

Know the Country-Spesific Status, Doctrines and Case Laws for Infringement

Rule of the law related patents may vary from country to country depending upon respective patent statutes, doctrines and case laws. Awareness well in this case is important point to consider the patent condition.

Search Patent Related Prior Art

The most critical aspect of FTO opinion involves examining the searched patent documents. By entering keywords usually will rise a thousand patent documents, although not all from these documents is relevant. For instance, the status of each short listed patent application must be checked out as only valid and enforceable patents and under prosecution patent application ought to be included in FTO opinion. Subsequently, a preeliminary selection based on the abstract and claims of the patent needs to be carried out.

Determining FTO Opinion

FTO opinion formed based on comprehensive and combination of results from each step. All information related patent such as date of application, publication, inventors, country scope, claims, field of technology must be considered systematically and accurately. Good results of FTO opinion will influence next execution of the technology transfer.

Case Study Determining FTO Opinion From Pharmaceutical Technology From Combination of Two Databased (PCT Application and Google/Patents)

US005162037A

United States Patent [19]

Whitson-Fischman

[11] Patent Number: 5,162,037

[45] Date of Patent: Nov. 10, 1992

[54] **MAGNETICALLY INFLUENCED HOMEOPATHIC PHARMACEUTICAL FORMULATIONS, METHODS OF THEIR PREPARATION AND METHODS OF THEIR ADMINISTRATION**

[75] Inventor: **Walter Whitson-Fischman**, New York, N.Y.

[73] Assignee: **Whitson Laboratories, Inc.**, New York, N.Y.

[21] Appl. No.: **696,759**

[22] Filed: **May 7, 1991**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 540,295, Jun. 19, 1990, abandoned, which is a continuation of Ser. No. 176,731, Apr. 1, 1988, abandoned.

[51] **Int. Cl.**[5] **A61N 2/00**

[52] **U.S. Cl.** **600/12**; 600/15; 128/907

[58] **Field of Search** 600/9, 12, 15; 128/907

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Primary Examiner—Lee S. Cohen
Attorney, Agent, or Firm—Edgar H. Haug; John M. Kilcoyne

[57] **ABSTRACT**

A method for treating pathogenic conditions of the human body by preparing a homeopathic mixture of at least one herb, herbal extract or other compound exhibiting therapeutic properties, adding a magnetically permeable substance to the mixture if necessary, magnetizing the resulting mixture to impart a substantially unipolar magnetic charge on the mixture and administering the magnetized mixture through one or more specific acupuncture points associated with producing a desired response to the particular condition being treated. The invention is also directed to the treatment of various diseases through the oral, auricular, topical or injectable administration of magnetically influenced homeopathic medicaments.

38 Claims, 3 Drawing Sheets

What is claimed is:

1. A method for treating pathogenic conditions of the human body comprising the steps of:

preparing a mixture of at least one herb, herbal extract or other compound having therapeutic properties to which a particular condition being treated is responsive;

adding a magnetically permeable substance to the mixture if necessary;

magnetizing the resulting mixture in a magnetic field during delivery to impart a substantially unipolar magnetic charge on said mixture; and

administering the magnetized mixture through one or more specific acupuncture points of the body which are associated with producing a desired response to the particular condition being treated.

2. The method of claim **1** wherein the mixture is magnetized in a magnetic field of less than ten gauss.

3. The method of claim **1** wherein the magnetized mixture is topically administered to the body.

4. The method of claim **3** wherein a therapeutic amount of the magnetized mixture is placed over at least one pair of bilateral acupuncture points on the surface of the body.

5. The method of claim **4** wherein the mixture is magnetized by placing a source of magnetic flux in proximity to the mixture while it is placed over the bilateral acupuncture points on the surface of the body.

6. The method of claim **1** wherein the magnetized mixture is injectably administered to the body.

7. The method of claim **6** wherein a therapeutic amount of the magnetized mixture is injected into at least one pair of bilateral acupuncture points of the body.

8. The method of claim **1** wherein the magnetized mixture is auricularly administered to the body.

9. The method of claim **8** wherein a therapeutic amount of the magnetized mixture is impregnated into metal rods inserted into a device fitted to be placed over the ear, the metal rods being located in said device such that the magnetized mixture is in contact with at least one auricular acupuncture point when the device is placed over the ear.

10. The method of claim **1** wherein the magnetized mixture is orally administered to the body.

11. The method of claim **10** wherein a therapeutic amount of the magnetized mixture is administered to acupuncture points in the mouth by means of an oral delivery device which is magnetically transparent and permeable comprising a rod portion connected to a porous ball portion, said rod portion being capable of accepting and holding a magnetic charge, and said ball portion being impregnated with an effective amount of

From these example, if users need technology in homeopathic pharmaceutical, first step is enter keyword to the menu in patent database. Many patent document will rise and select a relevan data from the tittle of invention (2). FTO status could be examined from patent document that have expired because limitation of protection, scope of teritorial from registration and feature of technology in claims. Patent expiration could be seen from date of patent application (1). Based on example, date of patent is November 10th 1992 that means already over from 20 years of protection. This patent status be public domain since November 10th 2012. Scope of teritorial where patent registered could be seen from location where these patent applied (3). For example, this patent document could not registered in Indonesia so users in Indonesia have possibility and chance to utilize this technology legally. Utilization of this technology also be done by analyzing scope of claims. If the users utilize and adopt the technology such as methods from patent document but have difference from essential feature in claim (4), it possibility permitted. So, FTO give chance and possibility to users can adopt and reproduce the technology freely and surely legal. Technology transfer occured without commercialization or licensing pathway. FTO that managed systematically and accurately will give many advantage in the future particularly in pharmaceutical technology transfer.

Acknowledgments and Legal Responsibility

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CONCLUSIONS

The patent search should be systematic, structured, documented properly will result accurate data. FTO analysis sources from patent search be able to map and manage technology that have freedom to operate status in all therapies and medicines aspects particularly process, composition, formulation, methods, apparatus related in pharmaceutical industry and so that stakeholders especially developing countries can be absorb and utilized in order to accelerate technology transfer.

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